This repor is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. **CERTIFICATE NUMBER:** 23-R-0059
CUSTOMER NUMBER: 723

FORM APPROVED
OMB NO. 0579-0036

Sanofi-Synthelabo, Inc
Sanofi-Synthelabo Research
9 Great Valley Parkway
Malvern, PA 19355

Telephone: (610) -889-6318

NOV 2005

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits		296		10	306
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(b)(6), (b)(7)c

DATE SIGNED 28 Nov 05

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

11 November, 2005

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Explanation of Category 'E' Animals

1. **Number of Animals, Species and Procedure Used:**

   Total: ten rabbits

   During a repeat dose reproductive toxicity study, one rabbit exhibited transient clinical signs 10 minutes prior to death. The second rabbit died immediately after dosing. During a different repeat dose reproductive toxicity study, one rabbit was euthanized after acute onset of clinical signs. A second rabbit was discovered dead after having been observed with the minimal clinical sign of decreased feces.

   During a single dose perivascular tolerance study, six rabbits experienced severe erythema at the test site of one ear at 24 hours and were euthanized at approximately 48 hours after dose administration.

2. **Justification for procedure:**

   The international regulatory process to approve new drug formulations and candidate drugs requires drug safety assessments. The goal of these studies is to investigate the safety assessment profile of new pharmaceuticals for human use. The administration of anesthetics, analgesics, or tranquilizers to the animals on these studies could interact and alter the results of the safety assessment studies.

3. **Procedure required by:**

   Agency: U.S Food and Drug Administration.
   Code of Federal Regulations
   Federal Food, Drug, and Cosmetic Act
   Chapter V, Subchapter A – Drugs and Devices: Section 505 (i) (1) (A)

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Customer ID and Site Address:

ID:723